Standards Resources and Premarket Use

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Learning Objectives

- Locate FDA-recognized standards
- Find CDRH guidances on the use of standards
- Identify and decipher a standards title
- Locate standards supplementary information
- How to use a standard in a medical device submission
- Identify the elements of a Declaration of Conformity

Standards Products

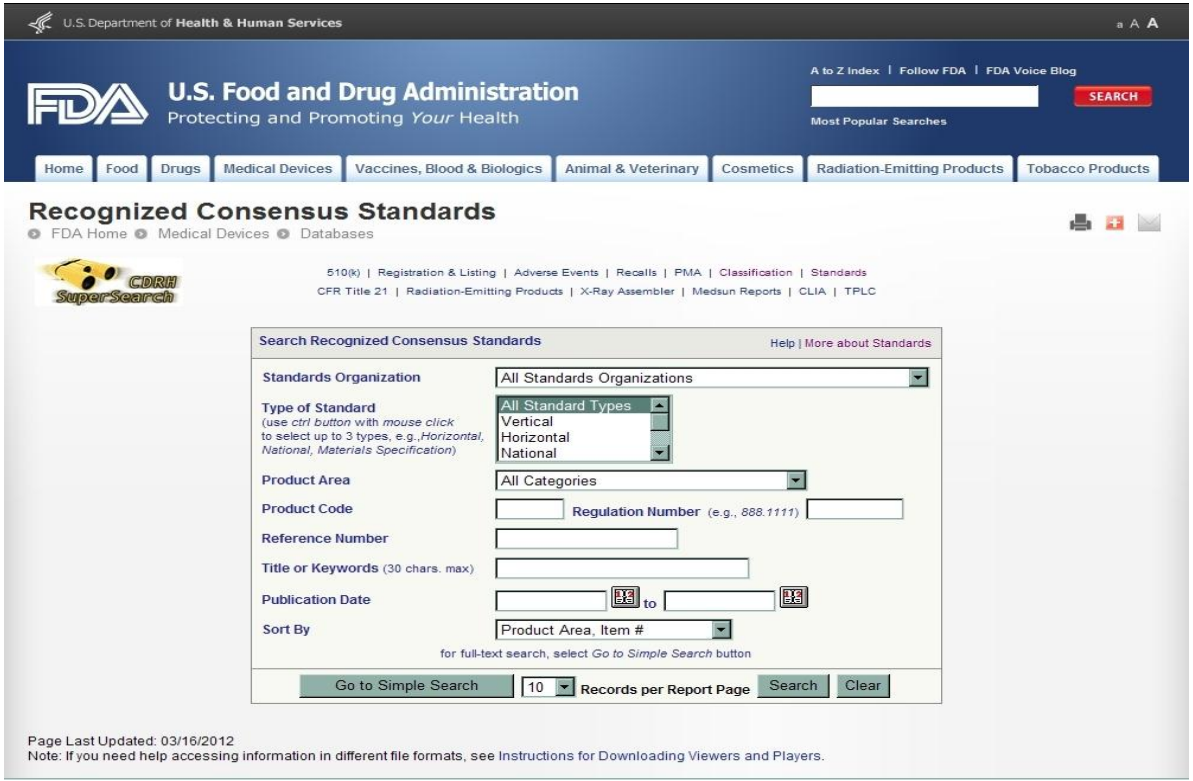
Each standard developing organization (SDO) produces differing types of standards from test methods to specifications to monographs to guidelines and technical information reports.

Knowing the type of standard utilized can inform on what types of data or other information should be included in a submission.

FDA Recognized Consensus Standards Database

- Repository for recognized standards
- Publicly available at www.fda.gov
- Supplemental Information Sheet (SIS)
  - provided for each recognized standard
  - identifies the device types addressed by the standard

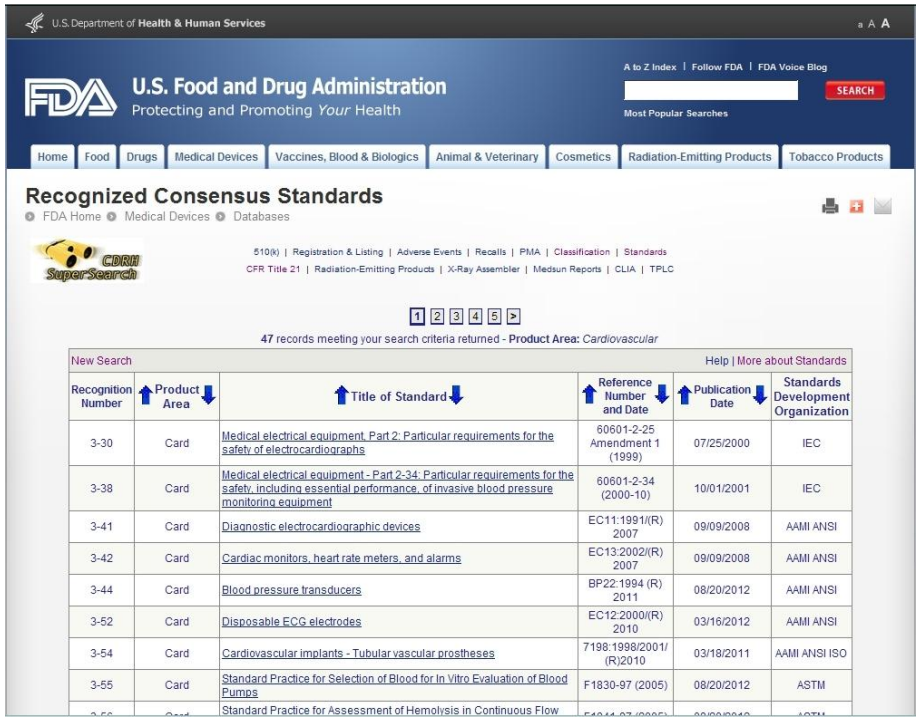
Consensus Standards Database



Search Capabilities

- Standards Organization
- Standard Designation Number
- Standards Title or Keywords
- Specialty Task Group
- Product Code
- Regulation Number
- Type of Standard
- FR List Publication Date
- Product Area

Sample Search: cardiovascular



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Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

Recognized Consensus Standards

FDA Home ▸ Medical Devices ▸ Databases

CDRH SuperSearch

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

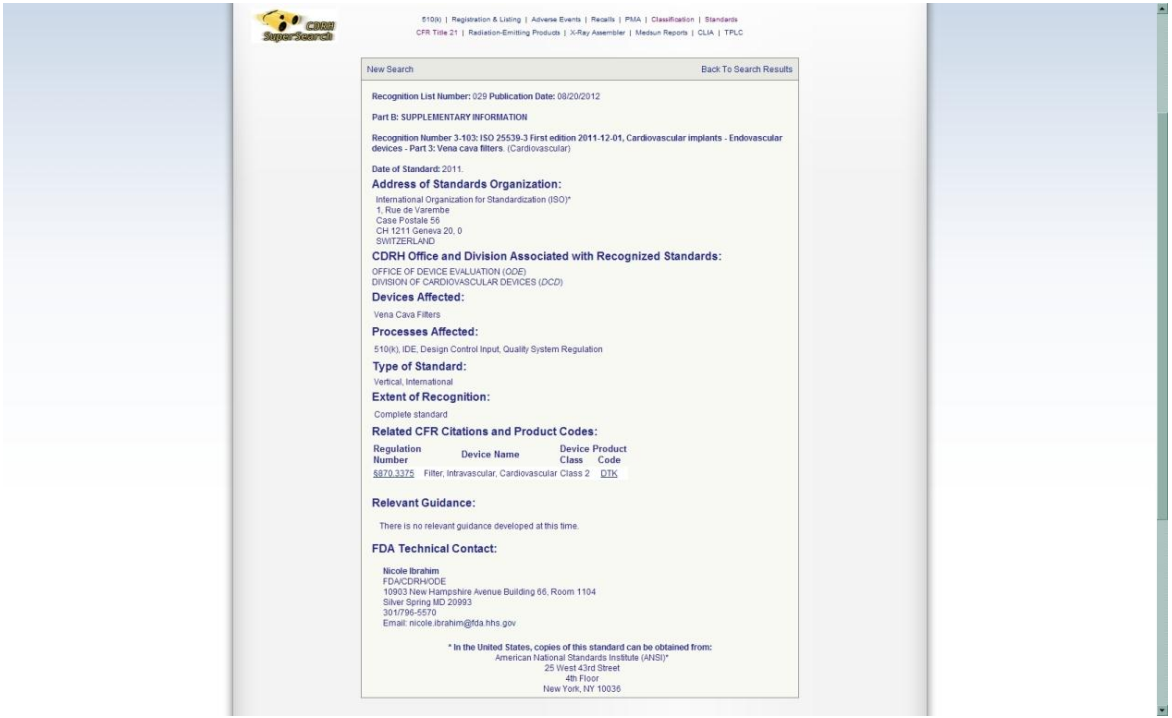
1 2 3 4 5 >

47 records meeting your search criteria returned - **Product Area:** *Cardiovascular*

New Search — Help | More about Standards

Recognition Number	Product Area	Title of Standard	Reference Number and Date	Publication Date	Standards Development Organization
3-30	Card	Medical electrical equipment, Part 2: Particular requirements for the safety of electrocardiographs	60601-2-25 Amendment 1 (1999)	07/25/2000	IEC
3-38	Card	Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment	60601-2-34 (2000-10)	10/01/2001	IEC
3-41	Card	Diagnostic electrocardiographic devices	EC11:1991/(R) 2007	09/09/2008	AAMI ANSI
3-42	Card	Cardiac monitors, heart rate meters, and alarms	EC13:2002/(R) 2007	09/09/2008	AAMI ANSI
3-44	Card	Blood pressure transducers	BP22:1994 (R) 2011	08/20/2012	AAMI ANSI
3-52	Card	Disposable ECG electrodes	EC12:2000/(R) 2010	03/16/2012	AAMI ANSI
3-54	Card	Cardiovascular implants - Tubular vascular prostheses	7198:1998/2001/ (R)2010	03/18/2011	AAMI ANSI ISO
3-55	Card	Standard Practice for Selection of Blood for In Vitro Evaluation of Blood Pumps	F1830-97 (2005)	08/20/2012	ASTM
		Standard Practice for Assessment of Hemolysis in Continuous Flow			

Example of a SIS



510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA | TPLC

New Search | Back To Search Results

Recognition List Number: 029 **Publication Date:** 08/20/2012

Part B: SUPPLEMENTARY INFORMATION

Recognition Number 3-103: ISO 25539-3 First edition 2011-12-01, Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters. (Cardiovascular)

Date of Standard: 2011.

Address of Standards Organization:

International Organization for Standardization (ISO)*
1, Rue de Varembe
Case Postale 56
CH 1211 Geneva 20, 0
SWITZERLAND

CDRH Office and Division Associated with Recognized Standards:

OFFICE OF DEVICE EVALUATION (*ODE*)
DIVISION OF CARDIOVASCULAR DEVICES (*DCD*)

Devices Affected:

Vena Cava Filters

Processes Affected:

510(k), IDE, Design Control Input, Quality System Regulation

Type of Standard:

Vertical, International

Extent of Recognition:

Complete standard

Related CFR Citations and Product Codes:

Regulation Number	Device Name	Device Class	Product Code
4870.3375	Filter, Intravascular, Cardiovascular	Class 2	DTK

Relevant Guidance:

There is no relevant guidance developed at this time.

FDA Technical Contact:

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FDA/CDRH/ODE
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Silver Spring MD 20993
301/796-5570
Email: nicole.ibrahim@fda.hhs.gov

*** In the United States, copies of this standard can be obtained from:**
American National Standards Institute (ANSI)*
25 West 43rd Street
4th Floor
New York, NY 10036

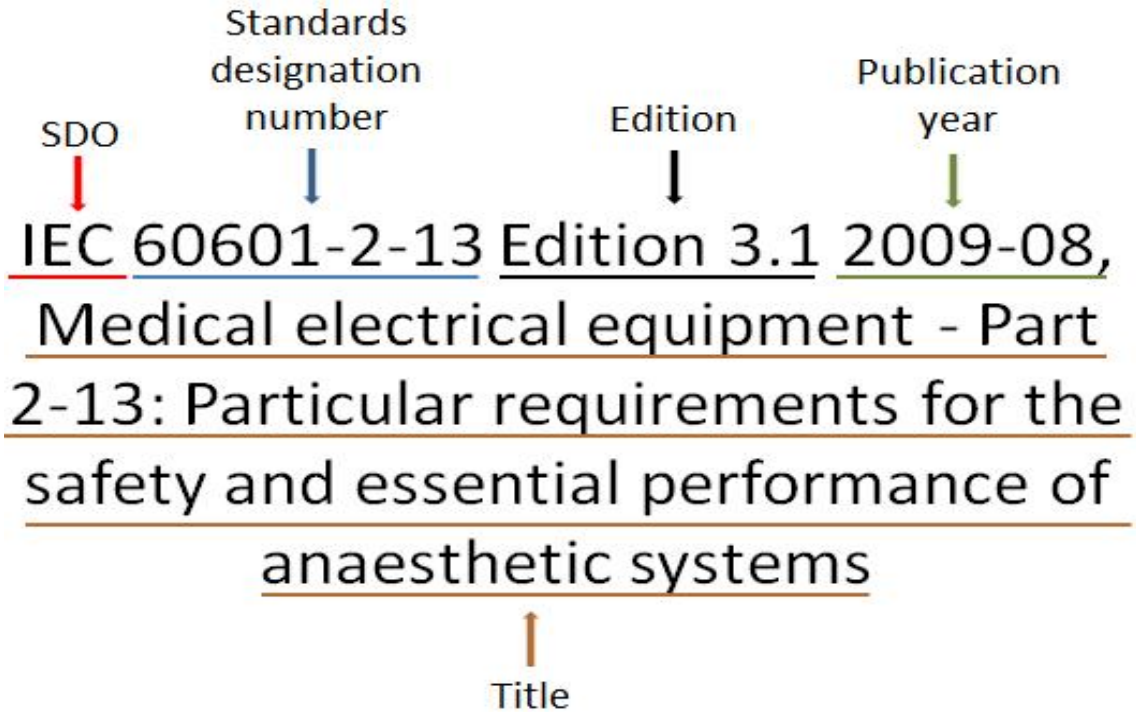
SISs

- FDA's determination of how a standard should be used in a premarket submission or other Center process
- Built-in latitude to support a standard even if some aspect conflicts with Agency position
- Standard may still be useful to the rest of the world even if not directly useful in review (practice guidelines)

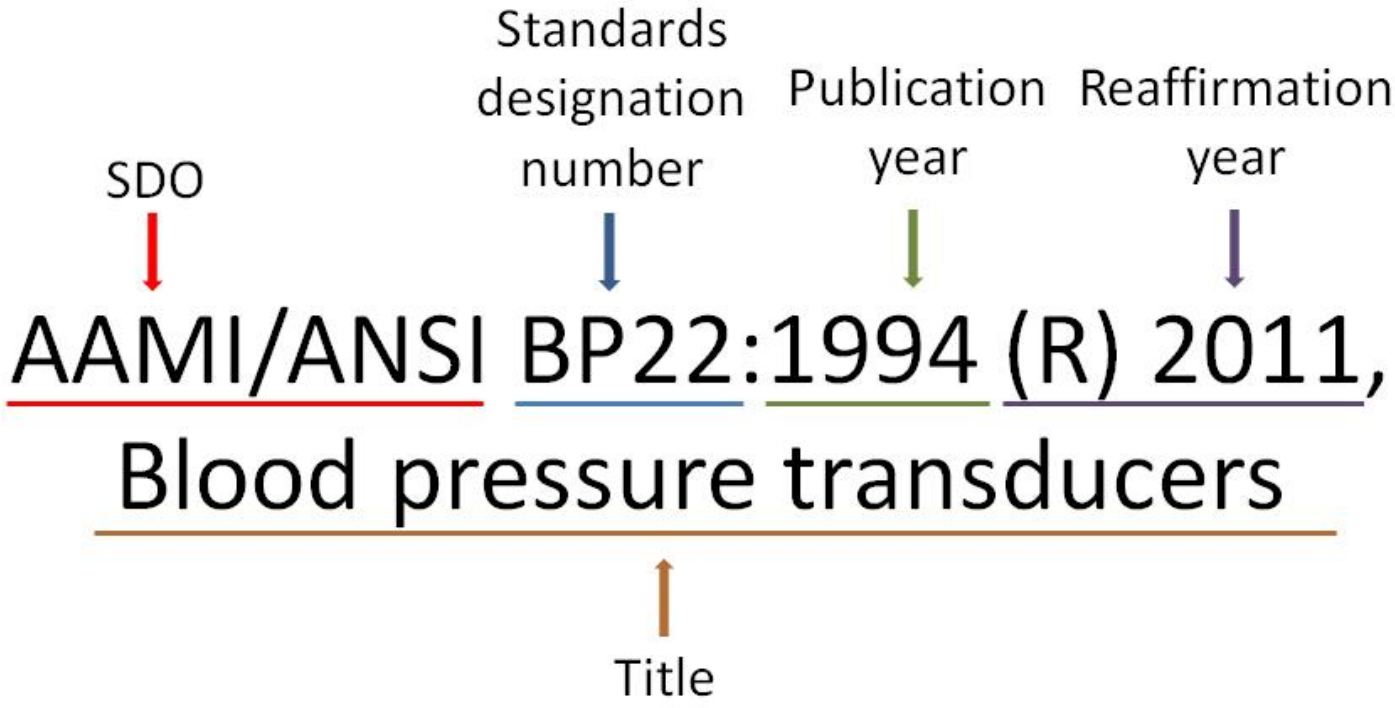
Information on a SIS

- Recognition List Number and FR Publication Date
- Recognition Number, Designation and Title
- Date of the Standard
- SDO address
- CDRH Offices and Division associated with the standard
- Devices Affected
- Processes Affected
- Type of Standard
- Extent of Recognition
- Related CFR Citations and Product Codes
- FDA Technical Contact(s)
- Relevant Guidances

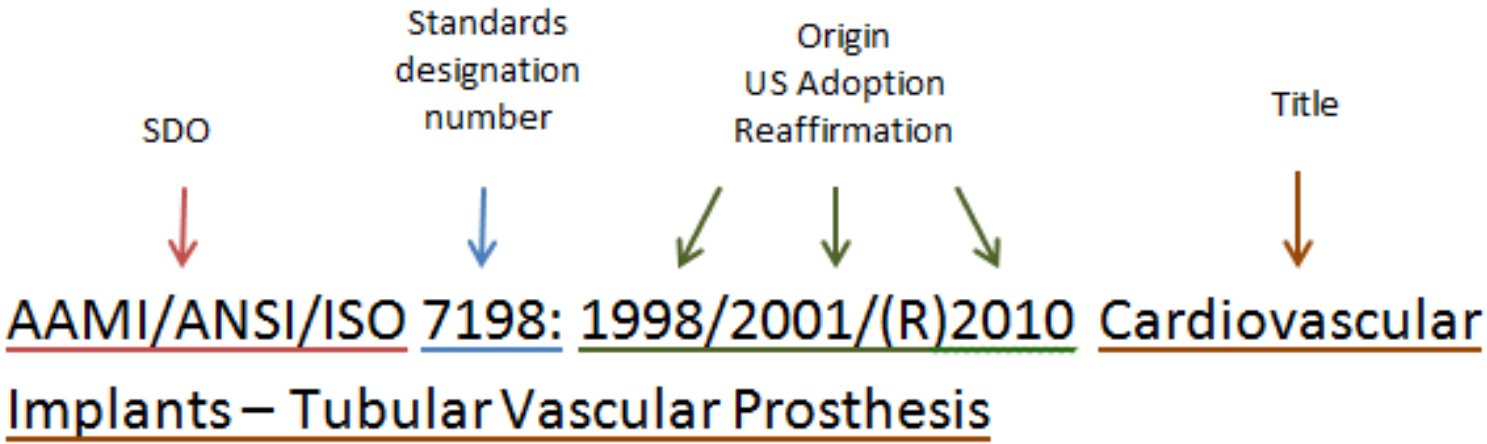
International Standards Title



National Standards Title



US Parallel Adoption



Standards Guidances

- Recognition and Use of Consensus Standards
- Use of Standards in Substantial Equivalence Determinations
- Frequently Asked Questions on Recognition of Consensus Standards

Two Ways to Use a Standard in Submissions

- General Use
- Declaration of Conformity

General Use

- When standards are used/cited without a declaration of conformity

- May use for any type of submission,
  - e.g., Traditional 510(k), PMA, IDE, *de novo*

Declaration of Conformity (DoC): when to use

Some standards lend themselves to a DoC without submission of a full test report

Examples:

- Standards with a test method
- Standards with test specifications or pass/fail criteria
- Standards with a pre-specified outcome

Declaration of Conformity (DoC): when not to use

Some standards require submission of full test report

Examples:

- Guidelines or Practices
- Technical Reports
- Technical Information Reports

7 Elements of a DoC

1. Identify the applicable recognized standard(s) that was met
2. For each standard, specify that all requirements were met, except for inapplicable requirements or deviations
3. Identify ways in which the standard was adapted
4. Identify inapplicable requirements

7 Elements of a DoC

5. Specify any deviations from each standard that where applied
6. Specify what differences exist between the tested device and the device to be marketed
7. Provide the name and address of each laboratory or certification body used

Documentation

- Standards often provide options or choices because there may be more than one method to assess the device
- The submission should explain how the standard was used, how it was adapted or modified to fit the device
- Was the device modified to fit the standard
- Was the entire device tested or not and why

Promissory Notes

- The circumstances in which it is appropriate to provide a “promise” to conform to a particular standard will depend on the standard and the subject device
- The test conditions and acceptance criteria need to be described beforehand
- If the results do not meet the agreed upon acceptance criteria or you had to modify the device to meet conformance a new 510k would be necessary

Summary

1. We reviewed how to find and locate FDA recognized standards.
2. We navigated the FDA website to search for specific guidances.
3. We reviewed the anatomy of the full description of a standard, and looked at samples of national, international, and US parallel adoption of international standards.
4. We reviewed the 7 elements of a Declaration of Conformity.
5. We discussed where standards can be used.